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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,527	02/12/2004	Udo J. Vetter	22767	5599

535 7590 03/22/2005

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EXAMINER

DESAI, HEMANT

ART UNIT	PAPER NUMBER
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3721

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

5P

Office Action Summary	Application No.	Applicant(s)	
	10/779,527	VETTER ET AL.	
	Examiner	Art Unit	
	Hemant M Desai	3721	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claim 11 contains the trademark/trade name "DATA MATRIX ECC 200", line 2.

Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe markings and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-5, 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin et al. (6813868) and Greenwald et al. (6597969) and further in view of Sleep et al. (6317648).

Baldwin et al. Disclose a method and apparatus for making pre-filled syringes by displacing a succession of syringes along a conveyor path from a supply station successively through a marking station (labeling station 80, fig. 5), a filling station (90, fig. 5), and to a downstream packing station (150, fig. 5), filling each of the syringes with a predetermined dose of a medicament in the filling station, marking (labeling) the syringes in the marking station (80).

Baldwin et al. fail to disclose the machine-readable mark to identify the medicament to be put in the syringe. However, Greenwald et al. teach to use the machine-readable mark (bar coded label) to identify the medicament to be put in the empty container (see col. 2, lines 21-57) to provide a medicament-dispensing system that compactly stores hundreds or thousands of different drugs and dispense the drugs accurately and efficiently for hundreds of patients (see col. 1, lines 48-55). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to having provided the machine-readable mark on the syringe (container) as taught by Greenwald et al. in the method and apparatus for making pre-filled syringes of Baldwin et al. to provide a medicament-dispensing system that compactly stores hundreds or thousands of different drugs and dispense the drugs accurately and efficiently for hundreds of patients.

The method and apparatus for making pre-filled syringes of Baldwin et al. as modified by Greenwald et al. and Greenwald et al. meets all the limitations of claim 1, except for scanning the marking (machine readable mark) before and after filling to reject the unacceptable syringes. However, Sleep et al. teach to scan the machine-

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readable mark before and after filling of medicaments (see figs. 9-10, col. 14, lines 10-37) to reject errant container. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to having provided the scanning the marking (machine-readable mark) before and after filling as taught by Sleep et al. in the method and apparatus for making pre-filled syringes of Baldwin et al. to reject errant container (syringes).

Regarding claims 2-5, the modified method and apparatus for making pre-filled syringes of Baldwin et al. teach to mark the syringes before production steps, and are scanned at several locations. It is well known that the barcode cannot read under normal light.

Regarding claim 12, the modified method and apparatus for making pre-filled syringes of Baldwin et al. meets all the limitations of claim 12.

4. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin et al., Greenwald et al. and Sleep et al. as applied to claim 1 above, and further in view of Kavanaugh (5919553).

The method and apparatus for making pre-filled syringes of Baldwin et al. as modified by Greenwald et al., Greenwald et al. and Sleep et al. meets all the limitations of claims 6-7, except for laser-inscribed markings on the syringes. However, Kavanaugh teaches laser-inscribed markings on a glass microscope slide to provide indelible machine-readable identifying information, which are capable of being scanned by a wide variety of conventional code readers (see col. 2, lines 3-17). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was

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made to having provided the laser-inscribed markings as taught by Kavanaugh on the syringes of Baldwin et al. to provide indelible machine-readable identifying information, which are capable of being scanned by a wide variety of conventional code readers.

5. Claims 8-10, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin et al., Greenwald et al. and Sleep et al. as applied to claim 1 above, and further in view of Mahar (6769228).

The method and apparatus for making pre-filled syringes of Baldwin et al. as modified by Greenwald et al., Greenwald et al. and Sleep et al. meets all the limitations of claims 8-10, except for rotating the syringe about their axis during scanning of the marking. However, Mahar teaches to rotate the bottles about their axis to allow the bar code information to be captured by the bar code scanner (414, fig. 4, see col. 10, lines 13-16). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to rotate the syringe about their axis during scanning of the marking as taught by Mahar in the method and apparatus for making pre-filled syringes of Baldwin et al. to allow the bar code information to be captured by the bar code scanner.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hemant M Desai whose telephone number is (571) 272-4458. The examiner can normally be reached on 7:00 AM-5: 30 PM, Mon-Thurs..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached on (571) 272-4467. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HMD



Rinaldi I. Rada
Supervisory Patent Examiner
Group 3700